FDA 510(k) Premarket Notification

CLEARED

K241129 Upper Arm Electronic Blood Pressure Monitor

Jul 3, 2024
70 days to decision

K241129 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k241129/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 24, 2024
Decision date	Jul 3, 2024
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Goodlymed Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Ma Maria
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Landlink Healthcare Technology (Shanghai) Co., Ltd.**
Contact	Kyra Kang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov